



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,276	12/09/2003	Alain Tornier	14542	2602
<div>293      7590      07/25/2007 Ralph A. Dowell of DOWELL &amp; DOWELL P.C. 2111 Eisenhower Ave Suite 406 Alexandria, VA 22314</div>				
			EXAMINER MCKANE, ELIZABETH L	
			ART UNIT 1744	PAPER NUMBER
			MAIL DATE 07/25/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/730,276

Applicant(s)

TORNIER, ALAIN

Examiner

Leigh McKane

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-19, 22-25, 27-30, 33 and 34 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 20, 21, 26, 27, 31 and 32 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-5, 8-19, 22-25, 28-30, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicolais (EP 982236) in view of Hamilton et al. (EP 737481) in view of Ahlqvist et al. (US 5,881,534).

With respect to claims 1-3, 8-11, 14-16, 19, 22-24, 28-30, 33, and 34, Nicolais teaches a process for the sterile packaging of a prosthetic implant **10** wherein the implant is placed in a flexible, gas-impermeable sachet **18** under vacuum (at a first pressure) and the sachet **18** is heat sealed. The sachet containing the implant is then placed within a flexible gas-impermeable outer envelope **20** which is also heat sealed. This sealed envelope **20** containing the sachet and implant is folded upon itself and placed within a rigid outer container **28** having a volume substantially equal to and a complementary shape to the sealed envelope to protect the implant. See Figure 2; paragraphs [0012]-[0027]. Nicolais is silent with respect to the implant (hip joint prosthesis) being made of polyethylene or to forming an inert gaseous atmosphere within the outer envelope before sealing.

Hamilton et al. discloses that it was known in the art at the time of the invention to fabricate artificial joints from polymeric materials, such as ultrahigh molecular weight polyethylene and to sterilize these joints using radiation. See Abstract; page 1, lines 7-10. It

Art Unit: 1744

would have been obvious to one of ordinary skill in the art to employ the sterile packaging method of Nicolais to package and sterilize implants fabricated from polyethylene since they are safely sterilized by radiation and since polyethylene is a common material from which artificial joints are fabricated.

Ahlqvist et al. teaches that when either an article or the packaging in which the article is enclosed is fabricated from a polymer, such as polyethylene, it is necessary to remove oxygen from the atmosphere surrounding the polyethylene so that during radiation the formation of free radicals is minimized. To remove the oxygen, Ahlqvist et al. discloses that the article or container in which it is held be surrounded by an inert gas (nitrogen). This is accomplished by sealing in an oxygen depleted atmosphere in the presence of an inert gas. See col.5, lines 19-25 and col.6, lines 40-52.

Since Nicolais *alone* teaches forming the envelope **20** of a polymeric material, such as polyethylene, it would have been obvious to form an inert gas atmosphere within the envelope **20** of Nicolais before sealing, thus minimizing free radical damage to the envelope itself. When sealing the envelope, it would have been obvious to do so within an oxygen depleted atmosphere, such as a vacuum, as taught by Ahlqvist et al. in order to remove all oxygen from the envelope. Furthermore, since the sachet **18** of Nicolais is under a vacuum, the pressure of the inert gas within the outer envelope **20** would necessarily be greater than or equal to the pressure within the sachet **18**.

As to claims 4, 12, and 13, Nicolais teaches that the sachet **18** may be formed of laminates of different materials (paragraphs [0020]-[0021]) but does not teach a laminate containing aluminum for the sachet **18**. Ahlqvist et al. discloses a gas-impermeable container

Art Unit: 1744

suitable for radiation sterilization that preferably contains an aluminum layer. See col.6, lines 41-47. A container having an aluminum layer would be necessarily opaque to visible light. It would have been obvious to one of ordinary skill in the art to choose a gas-impermeable packaging material known in the art to be sealable, stable over long periods of storage, and capable of withstanding irradiation. As the packaging material of Ahlqvist et al. meets these requirements and as Nicolais is not limited to a particular packaging material, it would have been obvious to one of ordinary skill in the art to choose the aluminum laminate packaging material of Ahlqvist et al. for the sachet **18** of Nicolais.

With respect to claims 5 and 17, Nicolais teaches that the envelope **20** can be fabricated from "flexible polymeric films" that are gas impermeable. Suggested materials include polyethylene and nylon (polyamide). See paragraph [0023]. However, Nicolais does not disclose a film containing both nylon and polyethylene. Hamilton et al. teaches sealed, gas-impermeable packaging material that is irradiated for sterilization of the articles within. Suggested materials include a multilayered film containing both nylon and polyethylene. See page 3, lines 6-14. As this packaging material fulfills the requirements of Nicolais (gas-impermeable, sealable, and radiation sterilizable), one would have found it obvious to use the packaging material of Hamilton et al. for the envelope **20** of Nicolais.

As to claims 18, 25, and 29, although the envelope **20** of Nicolais is disclosed to be flexible, it is placed within a rigid container **28** for protection during shipping and storage. It would have been obvious to provide further protection for the implant by fabricating the envelope of a semi-rigid or rigid material.

***Allowable Subject Matter***

3. Claims 6, 7, 20, 21, 26, 27, 31, and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. The following is a statement of reasons for the indication of allowable subject matter: Nicolais teaches sealing the envelope around the sachet, but does not disclose if the envelope is at a pressure less than atmospheric pressure. Ahlqvist et al. discloses using an inert atmosphere to protect a packaging material and sealing the packaging material in an oxygen depleted atmosphere but does not disclose maintaining the packaging material under a vacuum or a pressure at which the inert gas within the packaging material is kept. Thus, the combination of Nicolais with Ahlqvist et al. is silent to a pressure within the envelope that is less than atmospheric pressure.

***Response to Arguments***

5. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

Art Unit: 1744

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**Leigh McKane**  
**Primary Examiner**  
**Art Unit 1744**

elm  
21 July 2007